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Are Laparoscopic Staplers Effective for Ligation of Large Intraabdominal Arteries?

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Objectives. *To evaluate ligation of aortoiliac arteries with laparoscopic staplers in order to develop specifically designed staplers.*
Methods. Cadaveric study. *Seven human cadaver aortas were stapled using EndoGIA60® staplers. Efficiency was evaluated macroscopically and on a hydrodynamic bench.*
Clinical study. *Twelve patients had ligation of 14 large abdominal arteries (aorta: nine, iliac artery: four, hepatic artery: one) using a laparoscopic stapler. Stapling efficiency was judged on peroperative clinical and postoperative CT scan criteria.*
Results. Cadaveric study. *Stapling was performed perfectly on four moderately calcified aortas, without leakage with a pulsatile pressure of >250 mmHg. For three aortas with severe calcification, stapling was not efficient and major leakage occurred.*
Clinical study. *Stapling appeared clinically efficient on all arteries but one aorta: this severely calcified aorta was ligated conventionally. The staplers are not easy to use due to their shape and their lack of articulation. After a mean follow-up of 31.3 months, all the other stapled arteries were effectively ligated.*
Conclusion. *The commercially available staplers can be used securely on moderately calcified arteries but stapling of severely calcified arteries should be avoided. These devices should be redesigned to facilitate their use in vascular surgery.*

Key Words: Aorta; Ligation; Surgical staplers; Laparoscopic surgery.

As laparoscopy and other mini invasive vascular surgical techniques develop, the need for specific instrumentation grows. Staplers have been used for 20 years in general, thoracic and other types of surgery. We have used a laparoscopic approach for aortic surgery since 1998[1–3] and the ligation of large arteries appeared difficult to perform, using classical techniques. The goal of this study was to evaluate to what extent staplers can occlude the human aorta and iliac arteries, to facilitate the development of staplers designed for vascular surgery.

Methods

Ex situ *human cadaver aorta studies*

The experimentation took place in the department of Anatomy, Faculté de Médecine Nord, Université de la Méditerranée, Marseille, France.

Seven infrarenal aortas with both iliac vessels were removed from human cadavers, five men and two women, mean age 83 years (74–90). For each donor, height and weight were noted as well as the extent of the aortic calcifications (Table 1). Calcifications were judged as severe when there were found to be concentric. Measurements were performed with an electronic caliper rule on each vessel: internal diameter and thickness of the aorta. The side branches and one common iliac artery were ligated.

After removing the cutting blade, a Multifire Powered EndoGIA 60® stapler (Tyco Healthcare, Norwalk, Connecticut, USA) (Fig. 1(A)) was used to occlude the infrarenal aorta, by placing transversally six rows of 4.8 mm staples (Fig. 1(B)). The efficiency of the stapler was evaluated visually for occlusion of the aorta and transfixion of both aortic walls by the staples. To facilitate establishing the connection between the infrarenal aorta and the hydrodynamic bench, an 8 mm polyester graft was interposed between one common iliac artery on one side (end-to-end anastomosis using a 3–0 polypropylene suture)

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Table 1. Characteristics and measurements of the human cadaver aortas and results of stapling after placement on a hydrodynamic bench

Sex/age	Calcifications	Parietal thrombus	Internal diameter (mm)	Thickness (mm)	Occlusion	Transfixion	Pressure resistance without leakage
M85	Severe	No	15.9	2.7	No	Incomplete	Major leakage
M88	Moderate	No	16.2	4.0	Yes	Yes	>250 mmHg
M74	Severe	No	18.9	2.7	No	Incomplete	Major leakage
M92	Severe	Yes	16.0	2.6	No	Incomplete	Major leakage
M74	No	No	15.2	1.8	Yes	Yes	>250 mmHg
F78	No	No	13.4	1.9	Yes	Yes	>250 mmHg
F90	No	No	19.5	0.9	Yes	Yes	>250 mmHg

M, male; F, female.

and the bench on the other side (ligature around the tube).

Fig. 1(C) shows the hydrodynamic bench used to test the resistance to pulsatile pressure of the stapled aorta. A pressure measurement device was connected to the circuit. The stapled aorta had to be tested with a gradually increasing pressure of saline solution, up to 250 mmHg, for at least 2 min. In case of leakage, the output was measured.

Clinical study

Between 1998 and December 2003, 12 patients, with informed consent, were scheduled preoperatively for intra-abdominal arterial occlusion using a stapler in the Department of Vascular Surgery of the North University Hospital of Marseille. These 10 men and two women, mean age 65 years (ranging from 42 to 89) were operated for AAA in five cases (two endoaneurysmoraphy and three tripolar exclusion and axillobifemoral bypass in high-risk patients), left iliac artery aneurysm in two cases, aortic atheroembolism in three cases, aortoiliac occlusive disease in one case and one case of rupture of an intrahepatic aneurysm in a patient with Marfan syndrome and common hepatic artery (CHA) aneurysm. Surgery was performed through a laparoscopic ($n=5$) or a conventional access ($n=7$: transperitoneal five, retroperitoneal two). Stapling was performed on 14 large abdominal arteries: nine infrarenal aorta, four common iliac arteries (CIA) (one patient had both aortic and left common iliac artery stapling and one had bilateral CIA stapling) and one CHA. An EndoGIA 60® was used on the infrarenal aorta after removal of the cutting blade and a TA30® (Tyco Healthcare, Norwalk, Connecticut, USA) on the CIA and CHA (with a sleeve of PTFE in this last case). These devices were used with 4.8 mm staples.

The staples were considered efficient when there was no arterial pulse down to the staples lines and absence of bleeding on and through (when the artery was divided) the staples lines. Postoperative efficiency was assessed using CT scan. Follow-up was performed at 1, 3, 12 months and then annually.

Results

Ex situ *human cadaver aorta studies*

Aortic measurement data are reported in Table 1; no patient had an AAA. Internal diameter ranged from 13.4 to 19.5 mm (mean 16.4 mm). Mean aortic thickness was 2.4 mm (0.9–4.0 mm). Calcifications were found on four aortas, categorised as severe (circumferential) in three cases. Parietal thrombus was found in only one case.

Table 1 summarizes the results of aortic stapling with the EndoGIA 60®. The stapling was effective on four aortas, including three non calcified and one with moderate calcifications (Fig. 2):

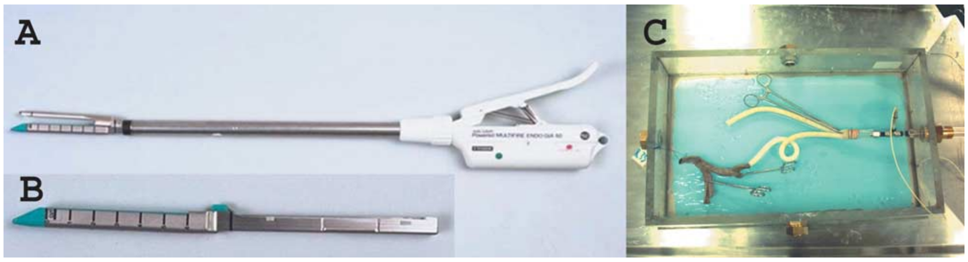

Fig. 1. Material: (A) multifire powered EndoGIA 60® (Tyco Healthcare, Norwalk, Connecticut, USA). (B) 4.8 mm staples for EndoGIA 60. (C) View of the hydrodynamic bench used for the experimental study.

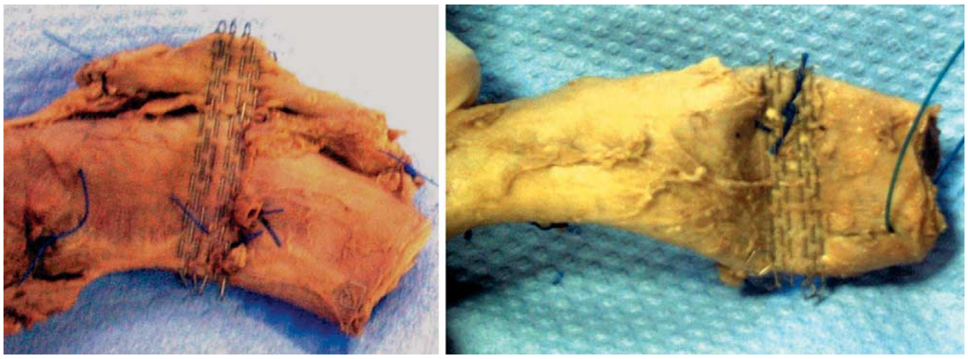

Fig. 2. Non calcified cadaver aortas: staples are released along the whole length of the aorta and are transfixiant.

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pressure resistance testing showed that there was no leakage with a pulsatile pressure of >250 mmHg.

However, for the three aortas with severe calcifications, the EndoGIA stapler was unable to release the staples along the entire length of the aorta and, therefore, unable to apply transfixiant staples to occlude the aorta (Fig. 3). We observed that the staples were correctly released at the proximal aorta but that on moving distally staples were progressively not perforating the aorta and by distal end staples were not even released. A major leak occurred when the pump of the bench was switched on.

In order to evaluate if this inadequate release of staples was due to the stapler's lack of power, we used a GIA stapler without removal of the cutting blade: despite this, it was still impossible to obtain complete and effective stapling of the aorta.

Clinical study

Table 2 summarizes the results of the clinical study. In all patients, stapling was performed. A PTFE sleeve was put around an aneurysmal CHA artery before stapling in the patient with Marfan syndrome. The stapler was not particularly easy to use due to the shape of the EndoGIA stapler and to its lack of articulation. Moreover, the tip of the stapler bumped up against the spine when used in an anterio-posterior axis. It appeared efficient, satisfying the clinical criteria on all except one artery (Figs. 4(A) and 5). This exception occurred in a high-risk AAA patient with a severely calcified proximal neck, scheduled for axillobifemoral bypass and tripolar exclusion. After stapling, the proximal neck remained open and it was ligated conventionally.

No perioperative deaths occurred. On postoperative CT scan, all the stapled arteries, for which stapling looked effective on the basis of the clinical criteria, were occluded effectively (Fig. 4(B)). No false aneurysm or other lesions were seen.

Mean follow up was 31.3 months (2–69.2). The patient, where the stapling device failed to exclude the AAA, died 7.4 months after surgery: during surgery for hip replacement at another center the axillobifemoral bypass occluded and the patient died 3 days after thrombectomy from multi organ failure. No other late complication occurred and no reintervention was needed. One further patient died at 37.2 months from

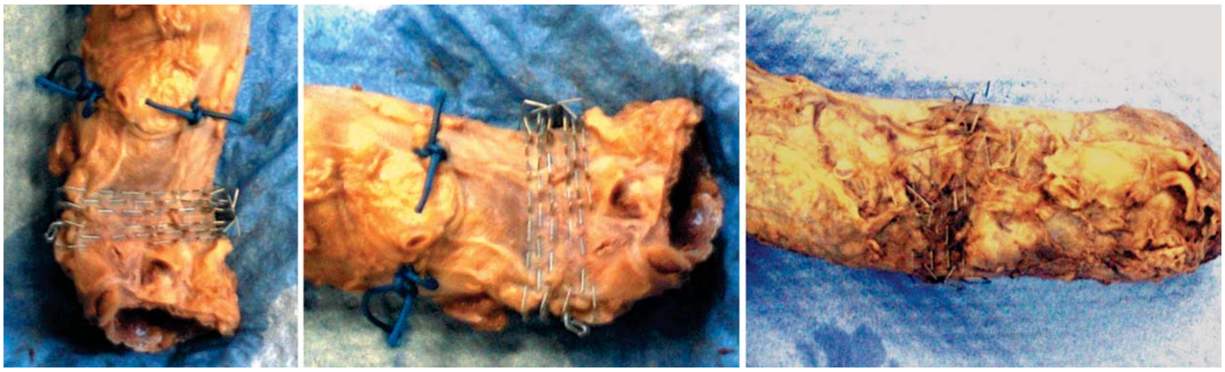

Fig. 3. Severely calcified aorta: the staples were not released at the distal half and those applied are not transfixiant and thus do not occlude the aorta.

Table 2. Patient characteristics and results of stapling

Sex–age	Pathology	Procedure	Stapled artery	Immediate result	Follow-up
M 57	AAA + AIOD	Laparoscopic ABFB	Aorta	Good	69.2 months
M 68	AAA biiliac	Laparoscopic ABFB	CIA × 2	Good	60.9 months
M 63	AAA	Laparoscopic ABIB	Aorta	Good	59.8 months
W 89	Ruptured AAA	AxBFB + tripolar exclusion	Aorta	Good	47 months
M 71	AAA	AxBFB + tripolar exclusion	Aorta	Good	Died at 37.2 months from pneumopathy
M 69	AAA	AxBFB + tripolar exclusion	Aorta	Conventional ligature	Died at 7.4 months from MOF
M 71	Aortic atheroembolism	RP ABFB	Aorta	Good	28.9 months
M 50	AAA left iliac	TP ARILFB	Aorta + LCIA	Good	25.5 months
M 53	Aortic atheroembolism	Laparoscopic ABFB	Aorta	Good	22.4 months
M 73	LCIA aneurysm	ALFB	LCIA	Good	17.9 months
M 42	CHA and intrahepatic aneurysm	CHA stapling	CHA	Good	9.5 months
W 73	Aortic atheroembolism	Laparoscopic ABFB	Aorta	Good	2 months

M, male; W, women; AAA, abdominal aortic aneurysm; AIOD, aortoiliac occlusive disease; LCIA, left common iliac artery, CHA; common hepatic artery; ABFB, aortobifemoral bypass; AxBFB, axillobifemoral bypass; ABIB, aortobiiliac bypass; RP, retroperitoneal approach; TP, transperitoneal approach; ARILFB, aorto right iliac left femoral bypass; ALFB, aorto left femoral bypass; CIA, common iliac artery; MOF, multiorgan failure.

lung disease. All late CT scans showed effective stapling without complications.

Discussion

Arterial stapling could be efficient in vascular surgery. Indeed, occlusion of the aorta and iliac arteries needs devices that provide reliable ligation of the artery without leakage. Moreover, these devices must be suitable for going around the vessels, especially the aorta. Such staplers are needed for laparoscopic aortic surgery, where conventional ligature of large arteries, especially pathological ones, is difficult but technical success is essential in order to avoid conversion. The need for stapling devices will be increased when anastomosing devices become available; their use will allow the performance of totally laparoscopic aortic surgery by any vascular surgeon, with cross-clamping times similar to those of open, minimal incision[1] or laparoscopically assisted[2–4] procedures.

Vascular stapling of pulmonary vessels is used commonly in thoracic surgery. Similarly, stapling has been reported on systemic vessels since 1982 when Blumenberg[5] first described the use of staplers for aortoiliac surgery (stump occlusion in end-to-end aortobifemoral bypass, ligation of iliac arteries in AAA). Ergin in 1983[6] proposed stapling for proximal AAA exclusion and Blumenberg[7] reported 100 cases of AAA, excluded by stapling, with aortobifemoral bypass using a retroperitoneal approach without any report of staple line hemorrhage: 11 patients had postoperative persistent flow in the AAA on ultrasound examination but six thrombosed during follow-up.

Different companies have commercialized stapling devices, initially designed for gastro-intestinal surgery, and laparoscopic models are available. Different sizes of staples can be chosen depending on the thickness of the tissues: 2.5 mm for vascular tissues, 3.5 mm for soft tissues and 4.8 mm for hard tissues. These sizes represent the height of the open staple and, for example, 4.8 mm staples have a closed height of 2 mm. In fact, the so-called 'vascular' staples cannot be

Fig. 4. Stapling of the distal aorta during terminal aortobifemoral bypass for occlusive aortoiliac disease: intraoperative view (A) and postoperative CT scan at the level of the staples (B) and under them (C).

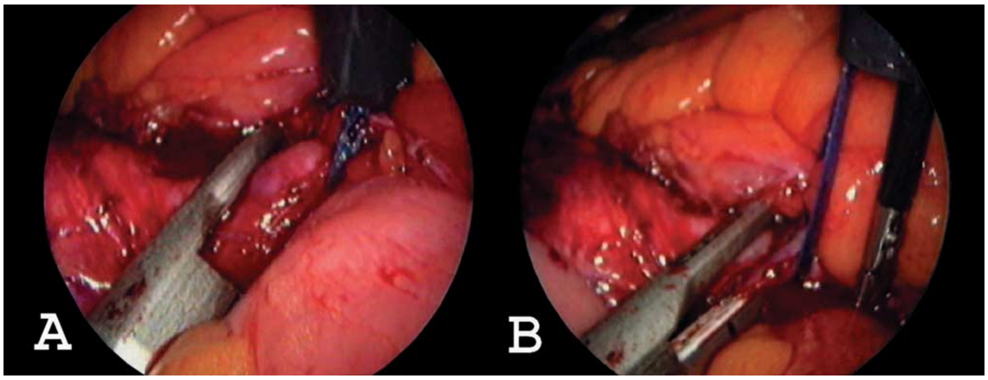

Fig. 5. Laparoscopic stapling of the left common iliac artery. (A) Placement of the stapler around the artery; (B) view after stapling.

used on pathological arteries (i.e. aneurysmal or occlusive disease): the thickness of the aorta in the cadaver study ranged from 0.9 to 4 mm with a mean value of 2.4 mm. The thickest wall needs staples made for 8 mm tissues to ensure complete transfixion. This is the reason why, we decided to use 'hard tissue' 4.8 mm staples, which are the largest available today. The vascular staples should be used only on non-pathological arteries, and not on severely calcified arteries.

Murayama[8] reported an experimental study of cadaver aortic stapling using a minimally invasive linear stapler with 4.8 mm staples and a sleeve of PTFE. He noted that stapling was effective in all except one case, where a 2 mm opening was found in an area of dense calcification. These results[8] confirm our own observations showing successful stapling of aorta with moderate calcifications, limitation of the technique in the presence of severe concentric calcifications. In heavily calcified vessels, we observed that staples were not released along the entire length of the stapling area and that most of those released were not transfixiant and so unable to perform arterial occlusion. This was confirmed by clinical results. We used the PTFE sleeve once only, to avoid arterial rupture on an aneurismal CHA in the patient with Marfan syndrome: no bleeding occurred.

Based on our findings, we believe that some modifications will have to be made to staplers in order to make them more suitable for aortic or iliac stapling. The stapler should be directional in order to facilitate the access to deep arteries like the aorta or the iliac; the new Roticulator EndoGIA® (Tyco Healthcare, Norwalk, Connecticut, USA) solves this problem. Further, current staplers do not apply staples on the distal tip: whilst having a blunt tip is beneficial in terms of iatrogenic lesions, in most cases, it bumps up against the spine and does not allow the posterior part of the aorta to be stapled when using the stapler in an anterior–posterior direction. One could argue that stapling could be performed in an oblique or lateral position: but coming from the left side would run the risk of tears on the inferior vena cava, and exposure of the aorta from the right side is not common. We, therefore, consider that curved end rotating staplers would be a more suitable design.

As far as stapling performances are concerned, we used a GIA stapler after removal of the cutting blade in order to obtain a ligature of six rows of staples. A stapling device for diseased arteries should have at least six rows of staples if not eight (although this would increase the width of the stapler and made it more difficult to introduce around the aorta). The largest length of the staples should be increased to 8 mm in order to extend use to thick arteries. Whatever the progress, severely calcified arteries will probably remain a challenging problem.

Conclusion

The staplers available commercially can be securely used on non or mildly calcified arteries. Stapling of severely calcified arteries should be avoided. Stapling devices should be redesigned in order to make them easier to use.

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